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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,152	04/20/2005	Daniel Mark Hickinson	100873-1P US	8232
44992	7590	11/29/2006	EXAMINER	
ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215				GODDARD, LAURA B
ART UNIT		PAPER NUMBER		
1642				

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/532,152	HICKINSON, DANIEL MARK	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 September 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3,5 and 8 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4,6,7,9 and 10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/05</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

1. The Election filed September 13, 2006 in response to the Office Action of June 14, 2006 is acknowledged and has been entered. Applicants elected the species of cells expressing **erbB2 and erbB3**.

A telephone call to Christine McCormack on November 14, 2006 confirmed election of the species of cells expressing erbB2 and erbB3 and that the response is incorrect in the election of cells expressing erbB1 and erbB3, which is not a species option. Christine McCormack also confirmed the inadvertent withdrawal of claim 4, on which the species election was based. Claim 4 will be examined as drawn to the elected species.

Claims 1-10 are pending. Claims 9 and 10 are amended. Claims 3, 5, and 8 are withdrawn as being drawn to a non-elected species. Claims 1, 2, 4, 6, 7, 9, and 10 are currently under prosecution.

***Specification***

2. The disclosure is objected to because of the following informalities: The specification does not provide section headings. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use:

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification should include section headings, for example: TITLE OF THE INVENTION, CROSS-REFERENCE TO RELATED

APPLICATIONS, FIELD OF THE INVENTION, BACKGROUND OF THE INVENTION, SUMMARY OF THE INVENTION, BRIEF DESCRIPTION OF THE DRAWING(S), and DETAILED DESCRIPTION OF THE INVENTION. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 1 is indefinite because it does not clearly state the objective of the method. The claim recites "A cellular proliferation assay for a compound acting through erbB-2". The preamble has no clear objective. A clear objective, for example, would be "A cellular proliferation assay for identifying a compound which acts through erbB-2", or "A cellular proliferation assay for identifying a compound that inhibits a ligand for erbB-3".

4. Claims 1, 2, 4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation step describing how the results of the assay relate back to the preamble of the method objectives. Claim 1 has no correlation step relating back to the preamble objective.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 6, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (Cancer Research, 2001, 61:4467-4473).

The claims are drawn to a cellular proliferation assay for a compound acting through erbB-2 which comprises:

- i) providing a cell comprising erbB-2 and erbB-3 and which is responsive to ligand stimulated cell proliferation under conditions suitable for cell proliferation;
- ii) providing a first ligand which is a ligand for erbB-3 capable of inducing proliferation by the cell;
- iii) contacting i) and ii) in the presence and absence of a compound; and
- iv) determining whether the compound has any effect on reducing cell proliferation (claim 1).

A cellular proliferation assay according to claim 1 comprising the addition of a control wherein the compound is tested in parallel in the absence of ligand to detect non-specific cell toxicity (claim 2), wherein the cell endogenously expresses erbB-2 and erbB-3 (claim 4), wherein the first ligand is heregulin (claim 6), wherein the first ligand is heregulin β1 (claim 7), wherein the cell is a MCF-7 cell (claim 10).

Lee et al teach a cellular proliferation assay wherein MCF-7 cells, which express erbB-2 and erbB-3, are contacted with erbB-3 ligand, heregulin  $\beta$ 1, in the presence and absence of a naturally occurring secreted human erbB-3 receptor isoform that inhibits heregulin-stimulated activation of erbB-2 and erbB-3, and wherein cell proliferation is measured (abstract; p. 4467, col. 2; p. 4468, col. 2; p. 4471, both columns; Fig 7). Lee et al contact the MCF-7 cells with the naturally occurring secreted human erbB-3 receptor isoform in the absence of the ligand to determine the effect on the cell proliferation (p. 4471, Fig. 7). Lee et al determine that the naturally occurring secreted human erbB-3 receptor isoform inhibits ligand-induced cell proliferation of MCF-7 cells. All the limitations of the claims are met.

6. Claims 1, 2, 4, 6, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ram et al (Cell Growth & Differentiation, 2000, 11:173-183, IDS).

The claims are drawn to a cellular proliferation assay for a compound acting through erbB-2 which comprises:

- i) providing a cell comprising erbB-2 and erbB-3 and which is responsive to ligand stimulated cell proliferation under conditions suitable for cell proliferation;
- ii) providing a first ligand which is a ligand for erbB-3 capable of inducing proliferation by the cell;
- iii) contacting i) and ii) in the presence and absence of a compound; and
- iv) determining whether the compound has any effect on reducing cell proliferation (claim 1).

A cellular proliferation assay according to claim 1 comprising the addition of a control wherein the compound is tested in parallel in the absence of ligand to detect non-specific cell toxicity (claim 2), wherein the cell endogenously expresses erbB-2 and erbB-3 (claim 4), wherein the first ligand is heregulin (claim 6), wherein the cell is an immortalized normal epithelial H16N-2 cell (claim 9).

Ram et al teach a cellular proliferation assay wherein H16N-2 cells, which express erbB-2 and erbB-3, are contacted with a erbB-3 ligand, heregulin  $\beta$ , in the presence and absence of a dominant negative form of HER3 and cell proliferation is measured (abstract; p. 174, col. 2; p. 175, col. 1; p. 177, both columns; Figure 10A, solid black columns in graph; p. 181, col. 2). Ram et al determined that the cell proliferation was inhibited in the presence of the dominant negative form of HER3. Ram et al teach said method wherein the H16N-2 cells are contacted with a dominant negative form of HER3 in the absence of the ligand and cell proliferation is measured (Fig. 10A, second set of bars, hatched column). All of the limitations of the claims are met.

7. **Conclusion:** No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER